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Original Research Paper

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A RANDOMIZED CONTROL STUDY OF PERINATAL OUTCOME FOLLOWING INDUCTION OF LABOUR WITH SUBLINGUAL MISOPROSTOL AND INTRACERVICAL PROSTAGLANDIN E2 GEL IN PRELABOUR RUPTURE OF MEMBRANE

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ABSTRACT

BACKGROUND: Premature rupture of membrane is a common condition, occurring in 5-10 % of all pregnancies. The standard practice in PROM is to induce labour within 6-12 hours of rupture of membrane to prevent chorioamnionitis that may be associated with high maternal and neonatal morbidity and mortality. **AIM:**To compare the perinatal outcome in PROM following induction of labour with sublingual misoprostol tablet vs intracervical prostaglandin E2 gel. **OBJECTIVES:** To compare the induction to delivery interval, mode of delivery and maternal and fetal complications between the misoprostol group and PGE2 group. **METHOD:** This is a randomized control trial done on one hundred cases , who were randomly allocated into two groups of 50 patients each. One group received Tab. Misoprostol 25 mcg 4 hourly upto 6 doses by sublingual route. Another group received Prostaglandin E2 gel 0.5 mg, given intracervically , repeated 8 hourly with maximum upto 3 doses. **RESULT:** In this study, the comparison between induction to delivery interval, need for oxytocin induction, mode of delivery and maternal and fetal complications were found to be statistically insignificant between two group. **CONCLUSION:** From the present study it can be concluded that none of the methods of induction of labour is superior to other. However, 25 microgram of sublingual misoprostol is more economical and easier method of induction of labour compared to PGE2 gel

KEYWORDS : PROM, MISOPROSTOL, PROSTAGLANDIN E2 GEL

INTRODUCTION:

Induction of labour can be defined as the stimulation of uterine contractions before the spontaneous onset of labour with or without rupture of membranes[1]. Successful induction of labour should result in onset of labour and progressive dilatation of cervix causing spontaneous vaginal delivery with minimal assistance along with minimum risk for maternal and fetal health within an acceptable time frame[2]. There are many methods of induction of labour which includes oxytocin infusion, prostaglandins like misoprostol, dinoprostone gel and surgical methods like stripping of membranes, artificial rupture of membrane, transcervical balloons etc[3,4]. Induction of labour can be achieved by using combination of both the methods[1]. The ideal inducing method is one that is safe for both mother and fetus, inexpensive, easily available and simple to administer. Prostaglandin analogue – Misoprostol and Dinoprostone gel both fulfill these criteria. Premature rupture of membrane is a condition in which rupture of membranes occurs in absence of uterine contractions irrespective of gestational age of the fetus. If rupture of membranes occurs after 37 completed weeks it is called as term premature rupture of membrane (PROM) and if occurs before 37 completed weeks it is called as preterm premature rupture of membranes (PPROM)[5]. Prelabour rupture of membrane poses important obstetric and neonatal complications. The management of PROM is best done by individual approach. The different methods are either expectant management and induction of labour. The standard practice in PROM is to induce labour within 6-12 hours of rupture of membrane to prevent chorioamnionitis that may be associated with high maternal and neonatal morbidity and mortality. The purpose of this study is to compare the perinatal outcome of induction of labour in primigravida women with sublingual misoprostol and intracervical prostaglandinE2 gel in whom prelabour rupture of membranes has occurred at term gestation.

AIMS AND OBJECTIVES:

Aim of the study was to compare the perinatal outcome in PROM cases following induction of labour with sublingual misoprostol tablet vs intracervical prostaglandin E2 gel.

Objectives were to compare the Induction to delivery interval, the mode of delivery and maternal and fetal complications between the misoprostol group and PGE2 group.

METHODOLOGY:

It is a randomized controlled study conducted from 1st April 2020 to 31st March2021 on primigravida between 37 to 42 weeks of gestation with vertex presentation with prelabour rupture of membranes admitted through antenatal OPD and emergency in Obstetrics and Gynaecology Department, Gauhati medical college and hospital. One hundred cases were selected and randomly allocated into two groups of 50 patients in each.Group A received Tab. Misoprostol 25 mcg by sublingual route. Group B received Prostaglandin E2 gel 0.5 mg intracevically.

- Tab. Misoprostol 25 mcg was repeated 4 hourly maximum up to 6 doses and Prostaglandin E2 gel 0.5 mg intracervically, 8 hourly maximum up to 3 doses until an adequate contraction pattern sets in (establishment of 3 uterine contractions in 10 minutes each lasting for 45 seconds with good relaxation in between) or cervical dilatation reaches 4 cm. Oxytocin augmentation was given in patients not having adequate uterine contractions (3 uterine contractions in 10 minutes each lasting for 45 seconds with good relaxation in between) during active phase of labour in both the groups. Augmentation was given according to low dose regimen i.e 2mU/min with increase @ 2mU every 30 minutes.

- Cases not having adequate uterine contractions or failing to go into active labour even after 6 doses of misoprostol or 3 doses of PGE2 gel were termed as failed induction.

- In all patients the cervix was assessed at the time of induction and before each dose and assessment was done by using modified Bishop's score.

ETHICAL CLEARANCE:

Clearance from Ethical committee of Srimanta Sankaradeva University of Health Sciences has been obtained.

RESULT:

In this study analysis of 100 cases of primigravida at 37-42 weeks of gestation with vertex presentation with prelabour rupture of membranes were done. Data from the case record proforma were entered into Microsoft Excel spreadsheet version 2016 and analyzed using IBM-SPSS version 24. Frequency and proportion (percentages) expressed the categorical data. Numerical data was represented with mean and standard deviation. For determining the statistical corelation in categorical data, a Chi-square test was applied. For normally distributed continuous data, a student t-test was applied, whereas, for non-normal continuous data, the non-parametric test of Mann-Whitney U was applied. P-value < 0.05 was considered significant for all statistical comparisons. The mean age in group A was 22.7±3 years and in group B is 23.4±3.8 years. In both the groups average age of gestation is 38 weeks 4 days. In Group A 80%(n=40) cases were booked and 20% (n=10) cases were unbooked and in Group B 72%(n=36) cases were booked and 28% (n=14) were unbooked. There is no statistically significant difference.

Table 1 : demographic profile

Age in years	Misoprostol		PGE 2 agel		Total		P Value
	n	%	n	%	n	%	
< 20	5	10	5	10	10	10	0.3214
20-24	32	64	29	58	61	61	
25-29	11	22	11	22	22	22	
≥ 30	2	4	5	10	7	7	
Booked	40	80	36	72	76	76	0.635
Unbooked	10	20	14	28	24	24	

In the present study, in group A minimum number of dose required was 1 in 4% of cases. Maximum number of dose required is 6 in 6% of cases and 48% required 3 doses. In group B minimum number of dose required is 1 in 28% of cases and maximum number of dose required is 3 in 26 % of cases and 46% required 2 doses. The difference was statistically significant(p=0.0001).

The average modified Bishop score at the time of induction in group A was 5± 1 and in group B was 4±1.The difference was statistically not significant (p value 0.2631). The average Bishop score 8 hours after induction in group A was 8±1 and in group B was 7±2 . The difference was statistically not significant (p value 0.0856). In this study, 21 cases (42%) in group A and in Group B, 22 cases (43%) required augmentation with Oxytocin.

Table 2 : Mean Bishop score

Mean Bishop score	Misoprostol	PGE 2 gel	P value
At induction	5±1	4±1	0.2631
At 8 hours	8±1	7±2	0.0856

The average duration from induction to delivery time in group A was 14±5 hours 25±15 minutes and in group B is 16±4 hours 30±14 minutes. The difference was statistically not significant (p = 0.4523).

For group A, 78% (39 cases) proceeded for normal delivery. 12% (6 cases) required LSCS and 10 % (5 cases) required instruments application for delivery (outlet forceps application in 3 cases and ventose applications in 2 cases). For group B, 82% (41 cases) proceeded for normal delivery. 10% (cases) required LSCS and 8% (4 case) required instrument application for delivery (outlet forceps application in 2 cases and ventose applications in 2 cases). In group A, there were 4% (2 cases) induction failure where as in Group B, it is 6% (3cases), in the present study. The difference was statistically not significant.

Table 3: Mode of delivery

Mode of delivery	Misoprostol		PGE2 gel		Total		P value
	n	%	N	%	n	%	
Normal	39	78	41	82	80	80	0.6511
Instrumental	5	10	4	8	9	9	
LSCS	6	12	5	10	11	11	

In group A, 80% (40 cases) exhibited clear liquor, 20% (10 cases) exhibited meconium stained liqour. In group B, 86% (43 cases) exhibited clear liquor, 14% (7 cases) exhibited meconium stained liqour.

In this study, 88% (44 cases) had no maternal complication, 6% (3 cases) developed fever, 2% (1 case) had nausea and vomiting 4%(2 cases) cases had tachysystole in group A. For group B, 96% (48 cases) encountered no maternal complication, 2% (1cases) mothers developed fever and 2 % (1 cases) mothers experienced tachysystole .

The difference was statistically not significant (p value 0.4523).

APGAR score of the neonate was recorded at 1 minute and 5 minutes after birth. For Group A, in our study, the mean APGAR score at 1 minute, was 6.6±1 and at 5 minutes was 8.6±0.7. In group B, mean APGAR score at 1 minute was 7.3±0.3 and at 5 minutes was 8.6±0.6.

In group A, 10% (5 cases) and in group B 8 % (4 cases) of neonates required NICU admission due to neonatal complication.

DISCUSSION :

Prelabour rupture of membrane is a common indication for induction of labour and most commonly used drugs are misoprostol and PGE2 gel. Cervical status always plays a significant role in successful induction of labour.

At induction, mean Bishop Score in misoprostol group was 5±1 and for dinoprostone group, the mean value was 4±1. After 8 hours, the Bishop score for misoprostol group had a mean of 8±1 and for dinoprostone group, the mean was 7±2 , the difference was statistically not significant (p value is 0.0856). In a similar study done by Veena et al[6] pre-induction Bishop score for misoprostol group was 3.32±1.274 and for dinoprostone group, the mean was 3.45±1.286. Post induction Bishop score for misoprostol group had a mean of 8.59±1.595 and for dinoprostone group was 6.77±2.195 , the difference was statistically significant (p value is <0.005).

In another study done Deepika et al[7] ,pre induction Bishop score was not significantly different but post induction Bishop score was significantly different between misoprostol group and dinoprostone group (p value <0.05). The difference may be because of difference in demographic distribution of patients, different indications of induction and different sample size .

In the present study, 21 cases (42%) required augmentation with oxytocin in group A and 22 cases (43%) in Group B. Deepika, et al[7], Rakhee R. Sahu et al[8] in their study found no significant difference in terms of need for augmentation of labour with Oxytocin between two Groups.

The duration of induction to delivery interval was one of the important outcomes of this study. In group A, average duration from induction to delivery time is 14±5 hours 25±15 minutes and in group B is 16±4 hours 30±14 minutes. The difference was statistically not significant (p value is 0.4523).

Jaya Vijaya Raghavan et al[9], Deepika, et al[7] , Herabutya Y et al [10] and Chaudhuri S et al [11] found mean induction to delivery interval with Dinoprostone and Misoprostol was statistically

insignificant.

There were no statistically significant difference between two groups in term of failed induction (p value 0.4231).

Chitrakar NS et al [12] found no statistically significant difference between two groups whereas Deepika, et al [7] found in misoprostol group, there were 12% cases of failed induction and in dinoprostone group, 6 % cases of failed induction.

In this study, there was significant difference in mode of delivery (p value 0.6511). Rakhee R. Sahu et al[8], Deepika, et al[7] and Chitrakar NS et al [12] found that there was no significant statistical difference in mode of delivery across the two Groups.

Common side effects of prostaglandins are nausea, vomiting, diarrhoea, uterine hyperstimulation, fever, tachycardia and chest pain. In group A, 88% (44 cases) had no maternal complication,6% (3 cases) developed fever, 2% (1 case) had nausea and vomiting 4%(2 cases) cases had tachysystole. In group B, 96% (48 cases) encountered no maternal complication, 2% (1 cases) mothers developed fever and 2% (1 cases) mothers experienced tachysystole. Jaya Vijaya Raghavan et al[9] found in misoprostol group 0.5 % cases had tachysystole, 1.5% cases had hyperstimulation,3.9% had vomiting,3.4% had diarrhoea and 1% case had hyperthermia. In dinoprostone group 2.9 % cases had vomiting, 2.9% cases had diarrhoea, and 1% cases had hyperthermia.

Rakhee R. Sahu et al[8] found no evidence of Gastro-intestinal side effects only 2% (1 case) from misoprostol group had fever

In the present study, In group A,10% (5 cases) and in group B, 8% (4 cases) of neonates required NICU admission due to neonatal complication. Deepika, et al[7] found in total, 19.5% of the cases required NICU admissions, of which 20 cases were from Group 1 and 19 cases from Group 2. The differences were statistically insignificant.

CONCLUSION:

From this study it was found that, there is no statistically significant difference between the two groups in relation to induction to delivery interval, mode of delivery and maternal and neonatal complications. Therefore, it can be concluded that none of the methods of induction of labour is superior to other. However, 25 microgram of sublingual misoprostol is more economical and easier method of induction of labour compared to PGE2 gel.

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